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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,675

01/29/2004

Tom McHale

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EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

09/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/767,675	Applicant(s) MCHALE ET AL.	
	Examiner Ryan Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 July 2008 has been entered.

Title

2. Examiner acknowledges the correction to the title has been made to say "Catheter Tip" instead of "Catherter Tip" per applicant's request.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 5, 6, 18-20 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Matthews et al. (4,739,769).** Matthews et al. disclose a catheter (see figure 6) having a shaft and a balloon (60) mounted thereon. The shaft has a distal portion, a central portion, and a proximal portion all having the same cross-sectional areas. First and second recessed portions (64 and 66) separate the distal, central, and proximal shaft portions. A radiused tip (65) is at the end of the shaft.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 2-4, 7-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Fulton (6,074,374).**

Matthews et al. do not disclose a marker or hub disposed beneath the balloon.

Attention is drawn to Fulton, who teaches a marker or hub (69) is disposed beneath the balloon to allow the balloon to be placed in the body in the correct place (centered at the treatment site) using well-known visualization techniques. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the marker hub of Fulton on the shaft beneath the balloon of Matthews et al. to allow for correct placement of the catheter and balloon at the treatment site.

7. **Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Fulton (6,074,374) as applied to claim 9**

above, and further in view of Follmer et al. (5,728,065). The combination of Matthews et al. and Fulton does not disclose a marker disposed flush with the outer surface of the catheter tip. Attention is drawn to Follmer et al., who teach a radiopaque marker (124) insert molded flush with the tip (see figure 2) to create a tip that has a low profile and can be imaged because the marker does not project radially outwardly from the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the

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time the invention was made to insert mold flush the marker of Follmer et al. with the tip of the combination of Matthews et al. and Fulton to create a tip that has a low profile yet can be located and guided using conventional imaging techniques.

8. Claims 12, 13, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Follmer et al. (5,728,065).

Matthews et al. do not disclose a first region and second region having differing flexibilities. Attention is drawn to Follmer et al., who teach a catheter tip may have two regions (122 and 114) with the second region (114) being less flexible than the first region due to the reinforcements therein (see column 7, lines 9 and 10), which creates a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tip of Matthews et al. of two regions wherein the first region is more flexible than the second region, as taught by Follmer et al., to create a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip.

9. Further regarding claims 12 and 13, the stiffer section has a spring (114).

10. Claims 16 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Follmer et al. (5,728,065) and Chee et al. (5,906,606). The combination of Matthews et al. and Follmer et al. discloses the invention as described in section 8 above. However, the combination does not disclose the second region is made of stiffening fibers of polypropylene or polyolefin. Attention is

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drawn to Chee et al., who teach a catheter tip may be reinforced with non-metallic materials (see column 7, lines 32-34) to create a device that has the rigidity desired yet is lightweight. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the fibers of the combination of Matthews et al., Follmer et al., and Chee et al. of polypropylene fibers or polyolefin fibers, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

11. **Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Imran et al. (5,766,203).** Matthews et al. do not disclose the catheter is a stent delivery catheter. Attention is drawn to Imran et al., who teach a balloon catheter can be used to deliver a stent to provide permanent support to a weakened vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the catheter of Matthews et al. as a stent delivery catheter, as taught by Imran et al., to deliver a stent to provide permanent support to a weakened vessel.

12. Regarding claim 22, Imran et al. teach a stent mounted about the balloon (see figure 8C).

13. Regarding claim 23, the stent of Imran et al. is an inflation expandable stent (see column 8, lines 36-41).

14. Regarding claim 24, the Imran et al. stent is self-expanding (column 8, line 56).

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15. **Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Hamilton et al. (6,514,228).** Matthews et al. do not disclose the catheter tip is shaped like a triangle. Attention is drawn to Hamilton et al., who teach an inner catheter tip may have a triangular cross section if desired. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the tip of Matthews et al. in a triangular shape, as taught by Hamilton et al., as an obvious alternative to the circular catheter shape.

16. **Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (4,739,769) in view of Follmer et al. (5,728,065) as applied to claim 15 above, and further in view of Chee et al. (5,906,606).** The combination of Matthews et al. and Follmer et al. does not disclose the second region comprises stiffeners that are carbon fibers. Attention is drawn to Chee et al., who teach a catheter tip may be reinforced with carbon fibers (see column 7, lines 32-34) to create a device that has the rigidity desired yet is lightweight. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the carbon fibers of Chee et al. to replace the metallic ribbons of Follmer et al. as the reinforcements in the second region to create a device that has the rigidity desired in the second region but reduces the weight of the device by using the carbon fibers instead of larger ribbons.

Response to Arguments

17. Applicant's arguments with respect to claims 1-26 and 58-60 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731